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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,899	06/12/2000	Neil T. Parkin	59597-A/JPW/JML/CMR	3775

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	8

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Appli ant(s)	
	09/591,899	PARKIN ET AL.	
	Examiner	Art Unit	
	Shanon A. Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *13-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of species election of group I and codon 88 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that groups I and II are not independent and examination of the entire application would not pose a serious search burden since the subject matter of the two groups are overlapping.

Applicant's arguments have been considered, but are not found persuasive because groups I and II are species and are not considered independent and distinct inventions. Further species requirements are drawn to different codon mutations. If the elected species, group I and codon 88 is found to be free of art, then a further search for subsequent codons within the elected species of group I will ensue. If all of the codons in elected species of group I are found allowable, then a further search for the species of group II with the elected codon will be examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 9, lines 2 and 3. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Also, page 154 is blank.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

The drawings are objected to because a description of individual figures 3a-3e, 4a-4e, and 5a-5e must be in the paragraph description under the Brief Description of the Drawings section and there is no brief description for Figures P and Q in the specification.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

Claims 1-79 of this application conflict with claims 1-79 of Application No. 09/663458. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-79 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-79 of copending Application No. 09/663458. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-112 and 114-117 of copending Application No. 09/766344 in view of Patick et al. (Antimicrobial Agents and Chemotherapy. 1998; 42 (10): 2637-2644). The object of the method and the method steps are identical in the instant application and '344. Application '344 does not teach specific codon mutations. However, Patick et al. teaches that the specific codon mutations in the instant claims are associated with decreased susceptibility to nelfinavir, but remained susceptible to amprenavir. One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate the codons of Patick et al. into the method of '344 to quickly evaluate the effectiveness of specific drug candidates.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 are unclear because it cannot be determined if the intent is really a two-step assay, involving a sequence determination followed by a drug sensitivity test, or if the intent really a one-step assay where the sequence at the recited codon is used to indicate drug sensitivity. If a two-step assay is truly intended, what is the point of evaluating the nucleic acid sequence, since the drug sensitivity test alone will accomplish the stated purpose of the assay? The claims state that the change in susceptibility is a decrease or increase in susceptibility to certain drugs. Is the intended meaning of the claims directed to determining whether mutations at specific codon combinations lead to a decrease or increase susceptibility to a specific drug, or do the instant mutation combinations actually denote a decrease or increase in susceptibility? The claims do not state that a drug in added in the susceptibility assay. Therefore, how could one make a determination based on the nucleic acid sequence alone?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assaying drugs to determine whether codon mutations indicate a decrease or an increase in drug susceptibility, does not reasonably provide enablement for predicting or determining whether a specific mutation denotes an increase or decrease in drug resistance to a specific protease inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

As discussed above, it cannot be determined from the claim language whether the intent of the claims is drawn to determining whether mutations lead to an increase or decrease in drug sensitivity or whether the claims are drawn to certain mutations denoting an increase or decrease in drug susceptibility. There is no teaching in the prior art that teaches a way to predict which codon mutations would indicate drug resistance and the specification supports this inability in teaching that a mutation at codon 90 cannot determine drug resistance. The specification does not describe the characteristics of a codon mutation that would indicate resistance to a specific protease inhibitor therapy. Therefore, due to the lack of predictability in the art to predict which codon mutations indicate drug resistance, the lack of teaching in the specification for predicting which mutations lead to drug resistance, the inability of the skilled artisan to immediately identify a codon mutation that indicates drug resistance, it is determined that an undue quantity of experimentation would be required of the skilled artisan to predict which drugs a patient will be resistant to based analyzing the codon sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Patick et al. supra.

The claims are drawn to a method for assessing the effectiveness of protease antiretroviral therapy of an HIV-infected patient by collecting a plasma sample from an HIV-infected individual, evaluating whether the sample contains a nucleic acid encoding a mutation at codon 88, 63, 77, 46, 10, 20, 36 or a combination thereof, wherein the patients were being treated with an antiretroviral agent. The mutations at codons 88, 63, 77, 46, 10, 20, and 36 encode a serine, proline or glutamine, isoleucine, leucine or isoleucine, isoleucine or phenyalanine, threonine or methionine or argenine, and isoleucine or valine, respectively.

Patick et al. teaches collecting a plasma sample from HIV-infected individuals treated with nelfinavir and evaluating specific amino acid residues mutations from the patients. Patick et al. identifies specific mutations at codons 88 to serine, 77 to isoleucine, 46 to isoleucine, and 36 to isoleucine. Patick et al. additionally teaches mutations at codons 63, 10, and 20. Patick et al. teaches that mutations at these specific codons correspond with resistance to nelfinavir, but retained susceptibility to indinavir and amprenavir. Although Patick et al. does not teach an increase in susceptibility to amprenavir, this characteristic would be an inherent property since

the structural mutations at the required residues are present. Therefore, the teachings of Patick et al. anticipate the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
March 21, 2002

James C. Housel 3/25/02
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